

REMARKS

Claims 1-9 are all the claims pending in the application. Claims 3-9 are withdrawn.
Claims 1 and 2 are rejected.

Claims 1 and 2 are rejected under 35 U.S.C. § 112, first paragraph as allegedly
“containing subject matter which was not described in the specification in such a way as to
reasonably convey to one skilled in the relevant art that the inventors, at the time the application
was filed, had possession of the claimed invention.”

Based on the use of the term “having,” it is the Examiner's position that the instant claims
encompass a large genus of nucleic acids directed to any pair of primers having sequences of
SEQ ID No.1 and 2.

The Examiner relies upon *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991)
to assert that, though Applicants are not required to disclose every species encompassed by a
genus, the description of a genus is “achieved by the recitation of a representative number of
DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the
claimed genus.” See Action at page 4, last paragraph.

Claims 1 and 2 are also rejected under 35 U.S.C. § 112, first paragraph, as allegedly
“containing subject matter which was not described in the specification in such a way as to
enable any person skilled in the art to which it pertains, or with which it is mostly nearly
connected, to make and/or use the invention.”

Again, due to the use of the term “having,” the instant claims allegedly encompass a set
of primers having SEQ ID NOs: 1 and 2 sequences, including primers that have extensions on 5'
and /or 3' ends of SEQ ID NOs:1 and 2.

Applicants respectfully disagree with the Examiner's analyses and conclusions set forth in

the Action.

Applicants respectfully submit with respect to the rejection under §112, first paragraph, that *Vas-Cath* is factually inapposite here as that case involved catheter designs comprising a pair of tubes (lumens). The question of whether the disclosure in *Vas-Cath* sufficiently described a genus of catheter designs cannot speak to a determination as to the sufficiency of the description of the primer sets claimed by Applicants.

Applicants submit further that the claims are not to be read in isolation but rather in view of view of the specification. In view of the disclosure as a whole, one skilled in the art would appreciate that the instant claims do not encompass a genus of nucleic acids directed to any pair of primers having sequences of SEQ. ID. No. 1 and SEQ. ID. No. 2.

Applicants submit with respect to both rejections under 112, that 1) the sequences subject of present claims and disclosure have been clearly described and that 2) one skilled in the art could practice the claims without undue experimentation.

The processes for making the claimed marker for purposes of identifying high artemisinin containing plants of *Artemisia annua* have been described in detail in the body of Applicants' disclosure. The methods which are described in detail, result in a marker which is linked to high artemisinin content.

The Examiner will kindly note the detailed steps set forth at pages 6-9 of the disclosure, which for the Examiner's convenience and for further clarification are re-stated in part herein.

Step 1. Plant improvement and selection (See disclosure at page 6)

The plants producing trace(0.10% or less) artemisinin and the plants producing more than 0.4% artemisinin were selected and finally 10 plants from each category were taken for DNA analysis.

Step 2: Analyzing the high (more than 0.4%) and low (less than 0.1%) plants for differential DNA fragments in the RAPD profiles. (See disclosure at pages 7-8)

The sequences of the primers MAP01 to MAP20 were:

AAATCGGAGC, GTCCTACTCG, GTCCTTAGCG, TGCGCGATCG,
AACGTACGCG, GCACGCCGGA, CACCCTGCGC, CTATCGCCGC,
CGGGATCCGC, GCGAATTCCG, CCCTGCAGGC, CCAAGCTTGC,
GTGCAATGAG, AGGATACGTG, AAGATAGCGG, GGATCTGAAC,
TTGTCTCAGG, CATCCCGAAC, GGACTCCACG, AGCCTGACGC, respectively.

The other sets of primers used included kit J, O and T, each consisting of 20 random decamer primers, procured from Operon Technologies Inc., USA.

These primers were used for RAPD analysis and the profiles were searched for fragments present consistently in the high artemisinin containing genotypes and low artemisinin containing genotypes.

The profiles generated with the primer CCAAGCTTGC provides such a fragment consistently present in the high artemisinin containing genotypes but absent in low artemisinin containing genotypes. We could detect a band at approximately 850 base pair region amplified with the primer 5'CCAAGCTTGC3' (MAP 12) which consistently showed its presence in the genotypes containing more than 0.4% artemisinin and absent in the genotypes with trace or no artemisinin. See pages 7-8 of the disclosure

Step 3: Isolation, cloning and sequencing of the 850-950 bp fragment based on which the SCAR primers were designed and synthesized

In the next steps, the DNA fragment described was eluted out from the agarose gel and (since the fragment was amplified with the primer containing Hind III restriction site) restricted with Hind III restriction enzyme (Recognition and restriction site 5'AAGCTT3'). Similarly, pBluescript II SK(+) procured from Stratagene Inc. was used to clone the fragment at the Hind III site.

The fragment was transformed into commercially available Escherichia coli strain DH5α.

The fragment was sequenced and end sequences were determined.

The end sequences were found to have the primer sequence at both the ends as random single decamer primer was used to get the distinct fragment. The primer sequence (CCAAGCTTGC) followed by 12 bases of one end TGAACGCATCGG was designated as forward primer (Sequence ID 1, 5'CCAAGCTTGC TGAACGCATCGG3') and primer sequence (CCAAGCTTGC) followed by 15 bases of the other end CACGCAGGCATTATC was designated as Reverse primer (Sequence ID 2, 5'CCAAGCTTGC CACGCAGGCATTATC3').

Step 4: Validation of SCAR primers to screen high artemisinin plants

These sequences added to the random primer specifically generated a 936bp fragment which was generated only in high artemisinin containing plants but not in low artemisinin containing plants. This was further confirmed by sequencing of the marker. See page 9 of the Disclosure.

Contrary to what is described in the disclosure, the Examiner proposes that the present claims encompass hypothetical sequences such as hypothetical sequence 5'ACCAAGCTTGC TGAACGCATCGGAAAAAAAAAA3' which Applicants have not described as primer sequence. One skilled in the art would understand, based on the disclosure, that the proposed sequence would not constitute a marker described by Applicants. Rather, the sequences described by Applicants based on logic, i.e. the random primer followed by the sequences drawn from sequencing both the ends, were used as SCAR markers for specific amplification.

One skilled in the art would readily appreciate the adequacy of the present disclosure and could readily practice the present claims in view of the same.

Withdrawal of the rejections under 35 U.S.C. § 112 is respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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